

NATIONAL FISHERIES INSTITUTE

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January 20, 2005

Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

200745 JFM 27

Re: Docket No. 2004D-0510 – Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association

The National Fisheries Institute (NFI) appreciates the opportunity to submit comments to the Food and Drug Administration regarding the proposed Referral Program for EU certificates of live and perishable fish and fish products. NFI has two main concerns about the proposed referral program: the availability of adequate National Oceanic and Atmospheric Administration Seafood Inspection Program (NOAA SIP) personnel to cover the additional certification requests and potential for significantly increasing the costs associated with obtaining certificates for export.

The National Fisheries Institute is the national trade association representing the diverse fish and seafood industry of the United States. NFI represents fishing vessel owners, aquaculturalists, processors, importers, exporters, distributors, retailers, and restaurants. Since 1945, NFI has been committed to providing consumers with an ample, safe, and sustainable supply of fish and seafood products.

NFI and its members support the work of the Food and Drug Administration (FDA) in providing food security and enabling the safe and efficient international commerce of valuable food commodities. NFI also recognizes that demand for EU Export Certificates has risen dramatically in recent years and is currently adding to the FDA's resource burden. However, NFI cannot support the proposed guidance, unless the agencies can assure that inspection resources are adequate to assure expeditious processing of certificate requests in all areas around the country and the criteria and procedures for issuing EU certificates will be processed in a manner consistent with current FDA procedures.

NFI supports the continuing role of the FDA as the primary competent authority for all EU-related Export Certificate services for fish and fishery products, as well as the FDA's continued guidance and oversight to the NOAA SIP with regard to EU-related Export Certificates. This role and function includes (a) establishing criteria for determining whether U.S. establishments are eligible to receive EU Export Certificates based on FDA establishment inspections and determination of the individual establishment's regulatory standing; (b) maintaining an up-to-date database on the current regulatory status of establishments (EU Export Certificate Lists); and (c) ensuring that the information from (a) and (b) is available to the NOAA SIP, so that it has the ability to issue EU Export Certificates.

NFI understands that the FDA is proposing to operate a 24 month referral program during which EU Export Certificates for all shipments of live and perishable fish and fishery products destined for the EU,

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EU Accession Partnership Countries, and EFTA Members would be issued by the NOAA SIP under the Agricultural Marketing Act. The basis for issuing EU Export Certificates under the referral program would be whether the establishment or establishments in question are in regulatory good standing with FDA. This service is currently offered by NOAA SIP nationwide for a fee that provides for cost recovery. At the end of the referral program, if it is deemed successful, the FDA intends to cease issuing EU Export Certificates for live and perishable fish and fishery products with this duty then to be borne by the NOAA SIP. During the referral program, both agencies intend to continue issuing EU Export Certificates for shipments of canned, frozen, dried, vacuum packed, etc. seafood products, as requested by appropriate parties.

NFI has two concerns about the upcoming referral program: adequate availability of NOAA SIP personnel and potentially increased costs of the service. NFI believes that the NOAA SIP will have difficulty servicing EU certificate requests in the State of Alaska and possibly in other areas of the country, including Hawaii. NOAA SIP does not have an inspector permanently stationed in Alaska, therefore, must contract with the State of Alaska for inspection services. NFI understands that there is one such inspector for the entire State.

NFI anticipates two significant impacts on exporters of live and fresh seafood, if the issuance of an EU certificate under the referral program is conditioned on a NOAA inspection prior to issuance of certificates. First, the processing and issuing of certificates will be delayed if inspections cannot be scheduled in a timely fashion. Delays of this type may have a cascade effect causing transportation and other logistical complications that might ultimately result in the deterioration of product quality and/or loss or cancellation of customer sales. In addition, the cost of exporting will increase measurably if NOAA SIP inspection is a requirement for certificate issuance. The existing hourly rates for NOAA SIP inspections are significant and in certain cases the inspection might occur at overtime rates if the certification process must be expedited to avoid transportation delays that can result.

The timeliness issue is especially relevant with live and perishable fishery products since they require airfreight scheduling with tight logistical and delivery timelines. A company that does EU seafood export business both from Massachusetts and Alaska confirms this observation. "There is always a huge crunch for time when doing a fresh export, whether it be in AK or MA. Consequently if we had to wait for an [NOAA SIP] inspector (if there even was one) to do this, it would most probably kill the whole business." They go on to state that, "To manage the export business out of MA we have a contract with the USDC to have an inspector on premises. It would be totally cost prohibitive to do the same in Alaska, once again, even if there was an inspector available."

The National Fisheries Institute appreciates the FDA effort to create a workable system that balances food security needs with the realities of international trade, but we cannot support the proposed guidance outlining the referral program without assurance of adequate service coverage in all areas from which EU seafood exports may originate. Moreover, if NOAA SIP were to assume responsibility for issuance of all EU Certificates regarding live and fresh fish the following conditions should be established:

1. FDA should remain the lead regulatory authority for commercial fish in the U.S., therefore, the referral program should be based solely on an establishment's eligibility for inclusion on the official FDA EU Export Certificate list; and

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2. NOAA's function should be primarily administrative (e.g. receiving the requests, checking to assure the firm is still in good regulatory standing with FDA and listed on the official EU Export Certification list, checking for accuracy and completeness of the certificate information provided by the exporter and signing the certificates) with an opportunity to charge a reasonable fee to recuperate the costs associated with the administrative tasks associated with issuing the certificates.

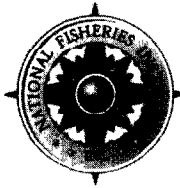
NFI believes that an unfair burden may be placed on exporters of live and fresh seafood in the absence of the conditions outlined above.

Thank you for your attention to these comments. Please do not hesitate to contact me if you have further questions or if I may provide additional information regarding our comments on this issue.

Sincerely,



Robert L. Collette
Vice President
Science and Technology
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